510(k) Summary k112824

JUN 2 1 2012

Summary Prepared Date: 04/12/2012

Submission Sponsor:

Quality Life Technologies Co., Ltd
No.5 Lao Fu Wu Road, Huang Wu Industrial District, Dong Keng Town,
Dongguan, Guangdong, P.R.China 523447

Submission Correspondent:

Mr. Leon Lu
Director of Quality and Regulatory Affairs

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Trade/Device Name:
Quality Life Technologies Compressor Nebulizer, Models NBA02-XXX
Common or Usual Name: Nebulizer (direct patient interface)
Device Class: II
Classification Name: Nebulizer (direct patient interface)
Regulation Number: 21 CFR 868.5630
Product Code: CAF
Review Panel: Anesthesiology

Predicate Device:

- K931015, DEVILBISS HEALTH CARE, INC. THUNGER TIGER CORP.
  DEVILBISS MODEL 4650 COMPRESSOR NEUBULIZER

- K870027, SALTER LABS
  HAND HELD PHEUMATIC POWERED (DISPOSABLE) NEBULIZER

- K052438, EMG Technology Co., Ltd
  EMG Handle Nebulizer NB02 Series

Device Description:

Our Quality Life Technologies Compressor Nebulizer works to convert the medication to a high-quality mist of fine particles and spray liquid medications in aerosol form into gases that are directly delivered to the patient.

Intended Use:

The Quality Life Technologies Compressor Nebulizer is an AC powered air compressor that provides a source of compressed air for home health care use. The product is used in conjunction with a jet (pneumatic) nebulizer to convert liquid medication into an aerosol form with particles smaller than 5 microns diameter for inhalation into the patient's respiratory tract for the treatment of respiratory disorders.

The target population for this device consists of adult patients suffering from, but not limited to asthma, cystic fibrosis, and chronic obstructive pulmonary disease. Further, additional applications for aerosolized medication are constantly under investigation and this device may be deemed suitable for such applications as prescribed.

The intended environment for use of the product is in the patient's home on the order of a physician.

Comparison to Predicate Devices:

Descriptive Information	Proposed Device	Predicate Device
510(k) Number	**NONE**	K931015
Manufacturer	Quality Life Technologies Co., Ltd	DEVILBISS HEALTH CARE, INC
Proprietary or Model Name	Quality Life Technologies Compressor Nebulizer, Models NBA02-XXX	DEVILBISS MODEL 4650 COMPRESSOR NEUBULIZER
Indication for Use	The Quality Life Technologies Compressor Nebulizer is an AC powered air compressor that provides a source of compressed air for home health care use. The product is used in conjunction with a jet (pneumatic) nebulizer to convert liquid medication into an aerosol form with particles smaller than 5 microns diameter for	The DeVilbiss compressor/nebulizer is an AC powered air compressor that provides a source of compressed air for home health care use. The product is used in conjunction with a jet (pneumatic) nebulizer to convert liquid medication into an aerosol form with particles smaller than 5 microns diameter for inhalation into the patient's respiratory tract for the treatment of respiratory disorders.

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Descriptive Information	Proposed Device	Predicate Device
510(k) Number	**NONE**	K870027
Manufacturer	Quality Life Technologies Co., Ltd	SALTER LABS
Proprietary or Model Name	Quality Life Technologies Compressor Nebulizer, Models NBA02-XXX	HAND HELD PHEUMATIC POWERED (DISPOSABLE) NEBULIZER
Indication for Use	The Quality Life Technologies Compressor Nebulizer is an AC powered air compressor that provides a source of compressed air for home health care use. The product is used in conjunction with a jet (pneumatic) nebulizer to convert liquid medication into an aerosol form with particles smaller than 5 microns diameter for inhalation into the patient's respiratory tract for the treatment of respiratory disorders. The target population for this device consists of adult patients suffering from, but not limited to asthma, cystic fibrosis, and chronic obstructive pulmonary disease. Further, additional applications for aerosolized medication are constantly under investigation and this device may be deemed suitable for such applications as prescribed. The intended environment for use of the product is in the patient's home on the order of a physician.	Hand Held Pheumatic Powered (Disposable) Nebulizer is to convert liquid medication into an aerosol form with particles smaller than 5 microns diameter for inhalation into the patient's respiratory tract for the treatment of respiratory disorders
Principle	Aerosolizes liquid into aerosol form by compressing air.	Aerosolizes liquid into aerosol form by compressing air.
MMAD	<5 micron Albuterol Sulfate (2.5 mg/3.0ml): 2.21	<5 micron Albuterol Sulfate (2.5 mg/3.0ml): 3.13

	Ipratropium Bromide (0.5 mg/2.5ml): 3.04 Cromolyn Sodium (20mg/2.0ml): 2.87	Ipratropium Bromide (0.5 mg/2.5ml): 3.10 Cromolyn Sodium (20mg/2.0ml): 2.40
Accessories	Tubing, Nebulizer Cup, Nebulizer Insert, Nebulizer Cap, Mouthpiece	Mouthpiece, T-piece, Cap, Medication Cup, Nebulizer Air-Inlet Connector, Baffle, Tubing
Target population	Adult patients	Both adult and pediatric patients
Environment use	In the patient's home on the order of a physician.	In the patient's home on the order of a physician.
Design	**Medication Cup Volumes:** Max. 5.0ml Device features: handy	**Medication Cup Volumes:** Max. 5.0ml Device features: handy
Performance	**Flow rate of compressor:** Max. flow rate of compressor is 9.9 (l/min) Max. pressure is 40.0 (psig) **Percent of drug does delivered which falls in the respirable fraction:** Albuterol Sulfate (2.5mg/3ml): 24.5% Ipratropium Bromide (0.5mg/2.5ml): 47.7% Cromolyn Sodium (20mg/2.0ml): 18.1%	**Flow rate of compressor:** Max. flow rate of compressor is 10.0 (l/min) Max. pressure is 40.0 (psig) **Percent of drug does delivered which falls in the respirable fraction:** Albuterol Sulfate (2.5mg/3ml): 53.5% Ipratropium Bromide (0.5mg/2.5ml): 48.0% Cromolyn Sodium (20mg/2.0ml): 29.5%
Biocompatibility	Biocompatible	Biocompatible

Descriptive Information	Proposed Device	Predicate Device
510(k) Number	**NONE**	K052438
Manufacturer	Quality Life Technologies Co., Ltd	EMG Technology Co., Ltd
Proprietary or Model Name	Quality Life Technologies Compressor Nebulizer, Models NBA02-XXX	EMG Handle Nebulizer NB02 Series
Materials	Same	Same

Discussion of Non-Clinical Tests Performed:

The performance requirements for Quality Life Technologies Compressor Nebulizer were met:

The patient contact components of the Quality Life Technologies Compressor Nebulizer met the requirements of ISO 10993 Part-1, "Biological Evaluation of Medical Devices".

Quality Life Technologies Compressor Nebulizer met the requirements of IEC 60601-1 and IEC 60601-1-2.

The performance of the Quality Life Technologies Compressor Nebulizer was tested by third party lab and demonstrated substantially equivalent to that of the predicate device.

Therefore, we conclude that the Quality Life Technologies Compressor Nebulizer is both safe and effective for its intended use.

Discussion of Clinical Tests Performed:

None

Conclusion:

The proposed device is as safe and effective as the predicate devices. The proposed device has the same intended uses and indications, similar technological characteristics, and principles of operation as its predicate device. The minor differences between the proposed device and its predicate devices raise no new issues of safety or effectiveness. Thus, Quality Life Technologies Compressor Nebulizer, Models NBA02-XXX are substantially equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Quality Life Technologies Company, Limited
C/O Mr. Leon Lu
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3500 South Dupont Highway
Dover, Delaware 19901

JUN 2 1 2012

Re: K112824
Trade/Device Name: Quality Life Technologies Nebulizer Compressor, Models NBA02-XXX
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: June 12, 2012
Received: June 15, 2012

Dear Mr. Lu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Quality Life Technologies Nebulizer Compressor, Models NBA02-XXX

Indications for Use:

The Quality Life Technologies Compressor Nebulizer is an AC powered air compressor that provides a source of compressed air for home health care use. The product is used in conjunction with a jet (pneumatic) nebulizer to convert liquid medication into an aerosol form with particles smaller than 5 microns diameter for inhalation into the patient's respiratory tract for the treatment of respiratory disorders.

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The intended environment for use of the product is in the patient's home on the order of a physician.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K172824